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AUG - 4 1995

Francis J. Tinney
Patent Department
Warner-Lambert Company
2800 Plymouth Road
Ann Arbor, Michigan 48105

Re: Patent Term Extension
Application for
U.S. Patent No. 4,376,858

#16

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,376,858 issued March 15, 1983, which claims the human drug product Neutrexin, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,284 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of August 30, 1994. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 \text{ (Testing Phase) + Approval Phase} \\ &= 1/2 (1,934) + 317 \\ &= 1,284 \text{ days}\end{aligned}$$


Since the regulatory review period began after the patent issue date, the entire period has been considered in the above calculation. No determination of lack of due diligence was made.

The limitation of 35 U.S.C. 156(g)(6) and the 14 year exception of 35 U.S.C. § 156(c)(3) do not operate to reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,284 days.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,376,858
Granted:	March 15, 1983
Applicant:	Norman L. Colbry
Owner of Record:	Warner-Lambert Company
Title:	2-4- DIAMINO-5-METHYL-6-[(3,4,5- TRIMETHOXYANILINO) METHYL]QUINAZOLINE SALTS
Classification:	544/291
Product Trade Name:	Neutrexin
Term Extended:	1,284 days


Gerald A. Dost
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

(703) 305-9285

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fisher's Lane, Room 11-044
Rockville, MD 20857

RE: Neutrexin

FDA Docket No.: 94E-0099